

Agency of Agriculture Food & Markets

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**Vermont Agency of Agriculture, Food, and Markets Comment to the Food and Drug
Administration on Rules Promulgated Under the Food Safety Modernization Act**

*Comments on proposed rules for Standards for the Growing, Harvesting, Packing, and Holding of
Produce for Human Consumption and Current Good Manufacturing Practice and Hazard Analysis
and Risk-Based Preventive Controls for Human Food.*

Thank you for this opportunity to provide comments on the proposed Produce Safety Rule and Preventive Controls Rule promulgated under the Food Safety Modernization Act (FSMA). Comments on both rules are contained within this document, with Produce Safety comments first followed by Preventive Controls.

The complexity and lack of specificity of both rules does not lend towards the ease of comprehension nor compliance. We find this concerning as the rules have far reaching impact on our agricultural communities. The New England structure of food production consists of small scale diversified farms distributing their local agricultural products to conveniently accessible markets. This production structure is uniquely affected by the proposed rules, particularly by the definition of ‘food’ including both human and animal feed and how that definition relates to thresholds and exemptions. Both proposed rules use gross ‘total food sales’ with food defined as “human and animal feed”. For example, farms that gross under \$ 500,000 annually based on their sales of produce would actually have a higher gross income as the definition of food would cause total food sales to include any hay sold, dairy production, maple syrup, meat, eggs alongside produce sales.

VAAFM has concerns regarding possible conflicts between compliance with the Rules and compliance with existing standards such as the USDA Good Agriculture Practices program, the National Organic Standards Program, and the Pasteurized Milk Ordinance. FSMA’s goal of improving food safety seems to be in conflict with USDA’s goal of increasing local food systems through small-scale agriculture and food hubs and could be problematic for community-based agriculture, which has been successful in New England and is growing through the nation. It is inefficient that FSMA requirements do not align with current food safety system requirements already in place through the market driven USDA Good Agricultural Practices (GAP) program. Clarification is needed on how the dairy industry, which is currently operating under the Pasteurized Milk Ordinance (PMO) will be impacted by this rule. FSMA’s proposed manure and

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compost application intervals provisions of nine-month and 45-day between application and harvest, respectively, is in conflict with the National Organic Standards (NOS).

Vermont Agency of Agriculture, Food and Markets (VAAFM) supports the premise of a food safety program and the regulatory authority needed for implementation. We recognize the exemptions and legislative limitations in the law. We acknowledge that due to the exemption of small-scale food producers, many operations involved in food production will not be captured by the rule. Consequently, the proposed FSMA structure will not adequately prevent food safety outbreaks nor lead to the development of a robust food safety system. We recommend that FDA allow the states to promulgate regulations that cover producers who fall under the \$500,000 exemptions and to provide the funding support needed to implement a compliance program that helps to ensure these producers are operating in accordance with minimum food safety standards

FDA needs to work with farmers and related stakeholders to clearly define needs in training, education, outreach and guidance. State Departments of Agriculture must be recognized as a valuable resource that should be involved in any contact, outreach or education with the farming community. VAAFM supports the mandate of FSMA to integrate state and local capacities and capabilities in the implementation of FSMA. The roles of agencies of agriculture and health are very unclear in regards to funding, implementation, education, and enforcement of the Rules. We recommend that FDA work with farmers and related stakeholders to clearly define needs in training, education, outreach and guidance. Additionally, we recommend education and outreach and technical assistance methods to ensure compliance prior to enforcement actions.

VAAFM highly recommends that FDA's next step be to publish a second draft of the Rules with an additional comment period as opposed to a final rule. We are hearing the concerns of our farming community and other stakeholders and it has become apparent that there is a lot of work to be done on the rules. These rules could potentially have drastic effects and unintended consequences on the farming community and regulated industry. Because there are so many areas that must be revised, we feel it is imperative that we have the opportunity to review and comment on the rules a second time before they are issued. The hasty promulgation of these rules, without an opportunity for a second comment period to review changes prior to issuance of a final rule, would be a disservice to the work of congress and the original intent of FSMA. Once a final rule is issued it is very difficult to change. Once the rules are made final our farming community and our food industry will be held to them, there will be regulatory

consequences for non-compliance. The issues that we have identified in the rule are important; they will have a significant impact on our farming community and our entire food production system from farm to fork.

Produce Rule

Second Comment Period

The rule should be re-released for a second public comment period after FDA incorporates the comments from the current comment period. As written, the rule will have drastic effects on agricultural practices throughout the country and VAAFM is concerned that it may have many unintended consequences. VAAFM supports the proposal that FDA analyze the comments that are received during the comment period and re-write the Produce Safety Rule based on these comments and close communication with stakeholders and state governments. This revised rule should then be posted for a second comment period prior to promulgating a final rule.

It is difficult to evaluate the cumulative economic and operational impact on our agricultural community without a clear understanding of what operations are included in the rule. Additionally farms and facilities are caught in unfortunately position of considering infrastructure investments and business growth decisions without the benefit of understanding how FSMA may impact their operation. A revised rule would give producers and processors a better indication of how or if they would fall within the rule and what specific compliance expectations would be required to help direct their food safety and business growth decisions. This comment reflects the previous comment on VAAFM not having a data collection mechanism to know who is or is not covered by either rule.

State Authority

State-level agencies need to have discussions with FDA about the state-federal relationship in terms of delegation of authority and who will be responsible for enforcement once the rules are in force. There is no reference made in the rule to the manner in which enforcement will be handled. VAAFM does not have the statutory authority to implement FSMA requirements or the jurisdictional authority to conduct a State Food Safety Program in compliance with the expected scope of FSMA.

Concurrent with the development of the federal rules, states need to be assessing the current division of roles and institutional relationships between agriculture and health for current food safety or food processing regulatory authority and any lack of authority to conduct a new food

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safety program in compliance with FMSA requirements. This requires involvement of FDA, as some level of consistency needs to be assured among the states. The anticipated timeline of one year for final FSMA rule release and less than three years to initiate FSMA implementation does not adequately account for the statutory and rulemaking process necessary at the state level to accept these authorities. VAAFM estimates a two year process to obtain legislative authority with an additional one year for rule promulgation.

Compliance protocols for FDA to implement the rules remains undefined and we question the role of FDA versus individual states regarding education, technical assistance, and compliance prior to enforcement. Additionally, it would be helpful to understand authority opportunities for customization allowances available to states.

Although the rules do not explicitly state how FSMA will be implemented, VAAFM suggests three possible options:

- 1) FDA implements and FDA inspectors carry out inspections and enforcement;
- 2) FDA delegates the compliance and inspections to state agencies; or
- 3) FDA uses its commissioning/credentialing structure and contracts with state agencies. If this option is used, we recommend it be transparent.

VAAFM recommends the development of FSMA compliant state food safety programs supported and funding by FDA. As states develop food safety programs at the local level, additional time will be required to promulgate rules and implement strategies for each process identified within FSMA. Related to this concern, FSMA does not identify the process for how regulatory and compliance authority will be delegated to individual states. It remains unclear the nature of the programmatic relationship between FDA and states and we consequently find it frustrating to engage in this level of conversation without this critical information. Additionally, no reference has been made regarding resources being provided for local implementation and state staff support.

The FSMA rules do not refer to or utilize any food safety framework that is already well established and with which producers and regulators are familiar. There are models in place that the FDA can mirror such as the USDA GAP audit structure and STAG (State, Tribal Assistance Grants) programs. It is not operationally sound to create a separate delegation or inspection framework for the FSMA program as producers will then be subject to complying with inconsistent sets of standards, depending on their market and their monetary average.

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Many growers currently work with and understand the GAP system and will likely not stop using the GAP audits since it is what their customers recognize and demand. It is our understanding that USDA is committed to revising their GAP Program standards to better align with FSMA requirements. VAAFM still remains concerned that producers will be expected to meet two food safety standards.

As another example, the STAG program is used to support state pesticide programs where federal funds are provided to states and used for regulation, education, certification, and training. A similar arrangement for FSMA could consist of an inter-agency overarching program with intra-agency jurisdictional pieces.

Resources and Funding

A comprehensive food safety program should include funding mechanisms, education, and producer-processor technical and financial assistance. FSMA has the potential to affect many producers never previously captured under a food safety regulatory program and will require support to meet minimum requirements. To implement this rule, states need a funding mechanism to offer compliance training programs, technical assistance, and infrastructure improvement to producer facilities. VAAFM requests that FDA provide more specifics regarding how the implementation of FSMA will be funded.

It seems unlikely that FDA will have adequate personnel and resources to cover the inspections and instead will rely on state resources to handle compliance with FSMA terms. Mobilizing these resources at the state level requires legislative interaction, possible rule promulgation, and hiring of inspection / business / legal staff. This process will likely not happen quickly, and this period is not accounted for in the proposed rule.

Federal funding is needed to assist farmers with infrastructure and equipment costs related to implementation of produce safety rules. Many producers in Vermont utilize older existing structures; for example, upgrading pack sheds, coolers and storage areas will be a huge investment and has the potential to impact business sustainability. Based on past experience with GAPs, the greatest compliance costs are associated with making pack sheds and storage areas (e.g. walk in coolers) cleanable. A significant percentage of Vermont's produce growers use old dairy barns as their wash and pack sheds. Rough estimates for upgrades are \$3-7 million. Again using GAPs as proxy, it could take up to two year for farm operations to come into compliance. USDA Rural Development initiatives (Know Your Food, Know Your Farmer for

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example) are designed to help grow local food systems. A similar initiative is needed to support producers through rule implementation.

Significant resources will be required for the training of regulators who will conduct inspections and provide training of industry, farm owners, and their employees. Businesses will need education on how to write plans, train employees, and make appropriate infrastructure improvements. Inspections should be uniform and consistent among federal and state officials conducting food safety assessments at the farm level. This can be accomplished through appropriate training, but FDA must consider funding mechanisms to state agencies for this purpose. States will require significant resources for legislative interactions and state rule promulgation along with the hiring and training of inspection staff, program staff, and legal staff.

A recommended solution would be an FDA developed fee-structure model or grant funded approach to assist state's preparation and implementation activities.

Education and Training

VAAFM recommends that FDA support an education and technical assistance program prior to enforcement. VAAFM supports education, technical assistance, and outreach for compliance prior to enforcement. The proposed rule is a new area of regulation for the federal government. Previously, FDA inspected farms when produce was suspected of contributing to a public health outbreak or when a farm also qualified as a food processing facility. Now, farmers that produce "covered" crops will be inspected. This new area of responsibility will take considerable thought, training, learning, education and understanding by all parties in order to implement. Technical assistance is limited within the state of Vermont. The University of Vermont Extension has one Outreach Coordinator who provides technical assistance on produce safety and there are only three known in-state private food safety consultants that operations can hire for assistance (one for GAPs and two for processing). VAAFM asks that FDA provide guidance on what will be considered acceptable employee training and also comment on and discuss available resources for states to provide training and technical assistance for each level of training required to implement and comply with the regulation.

FDA should provide more information on how they anticipate coordinating education and enforcement of the proposed regulation. Section 105(d) of FSMA requires FDA to "provide for coordination of education and enforcement activities by State and local officials, as designated

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190 by the Governors of the respective States,"; however, VAAFM has not received information or
191 communication regarding how the coordination of education and enforcement will function.

192 Please provide more detail on the recordkeeping requirements for producers and processors on
193 exactly what they need to keep records of. Based on GAPs experience, increased
194 recordkeeping requirements could add up to 3 hours of labor per week per operation.

195 Training: 112.22 (a) (3): Are farmers expected to train their workers in the specifics of the FDA
196 produce safety rules C through O?

197 112.22 (c): What curricula does the FDA recognize as adequate? We suggest the ability for
198 states to develop their own curricula.

199 **Exemptions**

200 What is the process for establishing an exemption – e.g., what proof does a producer need to
201 show regarding how the status of "exempt" was reached? Will FDA require farms to register if
202 they are seeking an exemption? How will FDA spell out this process? What will be the process
203 of removing a farm from exemption status? Regardless of how a farm is added or removed,
204 what mechanism will FDA use to provide information to relevant states? VAAFM has no data
205 collection mechanism for farm sales or production (operation size, products produces, income,
206 etc.) to help farmers determine if they are exempt from, or covered by, the Produce Safety
207 Rule. VAAFM requests clarification on FDA's intent for states to identify farms captured under
208 FSMA. The rules lack an obligation of the operation to provide self-determination data to
209 demonstrate compliance with particular categories. Is FDA considering self-reporting, tax
210 records, or sales data? This concern relates to the question of "How does FDA or VAAFM know
211 who is covered?"

212 FDA should be aware that the exemptions and tiers could become obsolete if the market
213 demands all places have some degree of food safety plan in place.

214 **Compliance Timeline**

215 The FDA is allowing businesses, depending on their size, more than one year to comply with the
216 rules. FDA must take into account the additional time needed to complete the inspections to
217 certify that they are indeed compliant.

219 Definitions and Terminology

220 Throughout the rules, numerous areas lack definition and specifics, making it difficult for
221 regulatory bodies to enforce the rules, as minimum standards are not detailed. The current
222 language in the draft rules for growers is very broad, and open to interpretation- such as:
223 "reasonable", "to minimize", "adequate", "periodic", "regular", "when necessary and
224 appropriate". There are no specific definitions given to these terms, which could result in
225 confusion among producers trying to comply and regulators trying to enforce.

226 FDA should consider modifying the definitions of "farm" and "harvesting" to allow some activity
227 with "others RACs" to take place and still remain within the definition of a "farm". Subparts K &
228 L of the Produce Safety Rule could then be modified to address activities with "others RACs".
229 This will allow farm level risks to be addressed in the Produce Safety Rule and not require farms
230 that are currently unregulated to be compliant with both the Preventive Controls and Produce
231 Safety Rule. The reason for this concern is that the proposed rules state "farm" and
232 "harvesting" activities can only be performed on commodities grown on the same farm or
233 another farm under the same ownership. These activities will be regulated under the Produce
234 Safety Rule. The same activities done on "others RACs" are automatically considered
235 "manufacturing/processing" and the firm is then classified as a "mixed-type facility". The
236 activities are then regulated under the Preventive Controls Rule. Creating arbitrary designations
237 of farms based on a definition that was not part of the enabling legislation is problematic. A
238 solution to this random dichotomy should be found, likely through an amendment to the law.

239 Definition of a farm: Current definition was created to exempt farms from the 2002
240 Bioterrorism Act and the lacks relevance to current modern farming practices and the produce
241 rule.

242 FDA should provide clarification on how a single business comprised of multiple farm premises
243 will be handled in the rule. The manner in which the term "farm" is defined in the context of
244 this rule is confusing for regulators and for regulated constituents. A farm is essentially defined
245 as a physical premises where RACs are produced, but the applicability of some terms of this rule
246 to different "farms" is made based on the total average monetary sales of the "business". If the
247 goal is to ensure that risk-based minimum food safety standards are met for all producers
248 (realizing that SOPs may vary from premises to premises within the same business), then the
249 rule should set thresholds based on quantifiable parameters associated with the premises

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250 (number of heads of lettuce produced) rather than on a monetary threshold associated with
251 the business.

252 If the “business” framework is retained in the final rule, the monetary threshold that defines
253 “very small” and “small”, etc. should be eliminated. Without having access to business tax
254 records (VAAFM does not have access to these types of records), it is impossible to prove an
255 average monetary amount. A possible solution would be to ensure that these thresholds are
256 based on something quantifiable that the farm is required to keep records on and that are
257 available for inspection by the regulator, such as volume or weight of produce. VAAFM
258 understands that a precedent exists for utilizing sales data to determine exemptions and
259 farmers may be more likely to capture sales data than quantities. VAAFM would like FDA to
260 provide solutions on how state enforcement agencies would be able to determine which size
261 categories farms fall into.

262 Proposed § 112.3(b) offers an overly restrictive classification of small and very small businesses.
263 The U.S. Department of Agriculture data shows farms below the gross-sale range of \$250,000
264 have a negative operating profit margin and a negative rate of return on assets and equity.
265 Given Congressional intent to ensure FSMA not pose undue burden to vulnerable farms, the
266 proposed definitions, based on overly high gross “food” sales instead of net revenue on raw
267 produce, fail to meet FSMA’s substantive provisions. The overall weight of these regulations will
268 severely limit the growth and viability of small and medium farm business operations, invariably
269 causing increased concentration among the largest, most risk-prone farms.

270 Please provide clarification if the definition of “food” includes food that is sold at a producer’s
271 farm that is not grown or produced on that same farm. An example would be items for sale
272 from farmers in the community held for sale at a farm stand located at another producer’s
273 farm. This is frequent practice at farm stands in Vermont and could have a significant impact on
274 farms depending upon the interpretation.

275 VAAFM has significant concerns regarding gross ‘total food sales’ with food defined as “human
276 and animal feed”. For example, farms that gross under \$ 500,000 annually (based on their sales
277 of produce) would actually have a higher gross income as the definition of food would cause
278 total food sales to include any hay sold, dairy production, maple syrup, meat, eggs alongside
279 produce sales. This inaccurate definition of the farms total food sales would make the farm
280 subject to the full force of the Rule and not eligible for exemptions as they should be if they

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281 were only selling produce. VAAFM recommends that the Rules refine total food sales
282 appropriately.

283 In regards to the Commodity List (Section 112.2), VAAFM recommends that it should not be
284 assumed that any particular vegetable is consumed in only the cooked state. Examples include
285 raw asparagus served as fresh snack at schools through the USDA Fresh Fruit and Vegetable
286 Program, shredded beets on salad, and baby kale and collards as salad greens.

287 Many farms have people who come onto the property but would never come in contact with
288 the produce. We suggest modification of the definition for “visitor” to account for this.

289 **Laboratory Resources**

290 VAAFM requests clarification as to whether required soil and water testing will be a program
291 run as a FDA program or state led program. VAAFM is concerned that states would need to
292 know new standard requirements to complete laboratory testing and are unsure how to
293 adequately prepare without understanding the new FSMA requirements. As our state’s lab
294 capabilities are limited, we seek guidance from FDA about how they will offer monetary and
295 logistical support to assist producers with required testing. We recommend that FDA support
296 state labs with monetary support, training, and capacity building to adequately process the
297 increased volume of testing.

298 VAAFM requests clarification on the following lab related requirements:

- 299 • Lab accreditation requirements for water and soil amendment samples,
- 300 • Funding for state lab services and lab staff.

301 **Agricultural Water**

302 Compliance with water quality standards promulgated in the proposed rule will be a great
303 challenge for many Vermont producers. Below is a list of varying concerns from producer
304 groups and university extension specialists related to water quality:

- 305 a. **Section 112.45 Agricultural Water.** The multi-part definition is cumbersome and
306 confusing. This creates trouble with specificity of sources and potential for multiple
307 intended uses. We recommend following GAPs standard that establishes a testing
308 schedule based on the type of water source (well, spring, surface water). Simplifying
309 testing schedule will increase producer compliance.

- b. **Watersheds.** Please clarify on how high up the watershed producers are responsible for monitoring for potential sources of contamination. Does the responsibility stop at the farmer's property line or does it extend to properties beyond the farmer's control. How high up the watershed are producers responsible for monitoring for potential sources of contamination? It would seem unreasonable to expect identification of sources of contamination. Can producers reasonably be expected to identify potential sources of contamination significantly further up the watershed?
- c. **Please explain the rationale for selecting the 7-sampling frequency.** Is the science based on different field and climate conditions or just in labs? If pathogens can get into the water at any time, why the frequency of 7 days (and not 6 or 14?).
- d. **Specify the circumstances in which water testing is required and at what frequency it is required.** Is the 7-day frequency specific to farms that use irrigation on a regular basis? Should these frequencies be modified for farms that only use irrigation on intermittent occasions? For example, should a farm that uses irrigation one day a month be testing at the same frequency as a farm that uses irrigation daily? The proposed rule seems to indicate that producer must test water "at the beginning of each growing season, and every three months thereafter." However, the table under 112.45 (b) seems to indicate if the water is from a river or lake, testing must be done every 7 days – or is that only if they suspect there is significant run-off? The seven day sampling requirement may be unattainable for producers using surface water; they may only request, receive, and irrigate every three weeks (taking into account the differences in water availability in American (riparian), Western and California water laws). Testing at the beginning of the season is realistic for determining critical issues followed by testing closer to harvest, which would be more critical than throughout the growing season. Testing irrigation water (if irrigating with surface water) every 7 days will be challenging for many producers in terms of both time and costs.

VAAFM hopes that FDA considers the following in regards to testing frequency:

- Find a way to recognize that not all surface waters are equal - some might be more likely to contain *E. coli* and some might be less.
- If the farmer is using the surface water for overhead irrigation of crops that are eaten raw, then they have to test frequently; if they are drip irrigating, the testing could be less frequent (especially if under plastic).

- Take a baseline reading at the beginning of the season and then adjust the frequency of testing based on that baseline.

- e. **Define what FDA considers the beginning of the “growing season”.** This term is used in several places in the Produce Safety Rule. What is generally known as the growing season contains a period of time where the edible portion of the produce is not yet present. Therefore, the requirement to start Agricultural water testing at the beginning of the growing season will cause confusion. VAAFM suggests that agricultural water testing not be required until the edible portion of the produce is present.
- f. **Please clarify the use of disinfectants.** All farms will need to add disinfectant and monitor disinfectant levels in their processing water, which will mean an investment in monitoring systems. It is not clear whether the standard requires water for dump tanks to have added disinfectant. It seems adequate, instead, for a producer to triple rinse produce and monitor *E. coli* levels of the wash water.
- g. **Clarify how the water testing requirements apply to water used to remove “field heat” from produce.** Please clarify if water resting requirements apply for taking out field heat (during harvest) or post-harvest. Continually monitoring post-harvest water that products are immersed in will require infrastructure/equipment costs of digital monitors. Some farmers take out field heat using dunk tanks in the field followed by the practice of rinsed the product again back in the pack house. The rule remains unclear whether a farmer utilizing the above method would have to continually monitor the water quality in a dunk tank used for removing field heat (especially if the farmer is then triple -rinsing/using sanitizer in the pack house).

Biological Soil Amendments

Please describe the science behind the “nine-month rule” for the time that must elapse between applying manure and harvesting. Northern states have shorter produce seasons than states further south and a nine-month provision may apply to an entire season or even beyond a full season for some crops. The nine-month interval is five months longer than the interval currently practiced by most farms and may present a real challenge for operations that are rotating livestock and do not have sufficient acreage to accommodate this interval, as well as farms that are getting manure sprayed on crop land. It would make sense for those states that experience a hard freeze and snow to be allowed an exemption in this area. The nine-month

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rule also seems in conflict with organic standards, principles of soil stewardship, as well as other federal policies for soil management and the improvement of organic matter/soil health.

In Part F of the proposed Manure regulations, the application methods described do not adequately encompass the variable application methods used in some states. This makes the “Application/Harvesting Intervals” section too restrictive. Has FDA determined the risk-benefit ratio associated with this proposal?

Does the science come from field vs. lab situations, signifying different soil conditions and climate conditions – especially for climates where there is a hard freeze and snow cover in-between application of manure and harvesting of crops? This rule provision could have a huge impact both on dairy operations in terms of manure management, and produce operations in terms of soil amendment management. It seems like it would be in conflict with organic standards & principles of soil stewardship, and perhaps with other federal policies re: soil management in terms of improving organic matter/soil health.

Wild and Domesticated Animals

FDA should consider additional scientific studies, and include provisions in the final rule that make clear the comparatively low and varying levels of risk posed by various animal species. The proposed rule fails to make clear that contamination from wild animals is a low risk factor as compared to contamination by other pathways and the probability for contamination differs based on the species of animal at issue. Questions abound as to the actual and perceived scope of the risk from wildlife and other animals contacting produce. Without a clear definition of the hazards required to be controlled, the ability of farmers and the state agencies to develop preventive controls is stymied. The proposed rule does not make clear the relatively low risk factor from wild animals as opposed to those from domesticated animals. Farm dogs and cats are used as working animals on an operation (usually for pest control and/or keeping other animals out of fields and outbuildings). If the farmer can demonstrate practices to reasonably minimize risk of excreta contaminating covered produce, are farm cats and dogs allowed on produce farms under these rules?

Food Hubs

We encourage FDA and USDA to increase their communication and collaboration regarding their goals for improving food safety through FSMA and also strengthening local food systems through small-scale agriculture and food hubs, which currently seem to be in conflict with each

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other. In Vermont, food hubs offer aggregation, storage, and distribution services for a wide variety of agricultural food products, including: produce, meats, dairy products, and processed items like pesto, pickles, and jams. Local foods from numerous operations are picked up or brought to a central storage and/or processing center before being distributed to the end consumer. The end consumer can be anyone from an individual household, workplace, institution, or retail outlet. Sometimes the food hub takes ownership of the product directly from the producer, while in other circumstances the food hub serves more of a brokering role between the producer and consumer.

Vermont has many small food producers that rent commercial processing space at a food hub or shared-use kitchen. These food hubs may also store packaged product, store refrigerated or frozen products, or store produce in cold storage for multiple businesses. Ownership of the food product may belong to the business owner, with the food hub providing commercial storage space and/or equipment. This model has been very successful in Vermont and has allowed small-scale producers access to properly constructed and maintained commercial kitchens that meet the current good manufacturing practices standards. Various Vermont food hub models also provide properly refrigerated distribution options and aggregation services allowing individual producers to access larger, wholesale markets. Better clarity on how facilities offering these critical supply-chain services fit into the new regulatory framework is needed.

Based upon the above described roles of food hubs, how will commercial food hubs fit into the Produce rule, Preventive Controls rule, and definitions of “qualified facilities”? Will they be covered by both rules? What will determine their inclusion in one or the other? How will total food sales be calculated for product aggregated at the food hub scale but still owned at the producer level? Will both producers and food hubs be categorized as “qualified facilities”?

Preventive Controls Rule**Pasteurized Milk Ordinance**

Clarification is needed on how the dairy industry, which is currently operating under the Pasteurized Milk Ordinance (PMO) will be impacted by this rule. In 21 USC § 350g (n) (5), FSMA directs FDA to ensure its regulations will be consistent with applicable domestic and internationally recognized standards. The PMO has been the effective nationwide industry standard since 1927, and has a proven track record of ensuring the safety of the nation’s milk

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supply. Grade "A" milk and milk products are subject to substantial oversight and regulation by the states, in close cooperation with FDA, pursuant to the NCIMS program. The Grade "A" milk industry is subject to quarterly state inspections including extensive pasteurization system tests to ensure compliance with the PMO. States have the authority to conduct compliance and enforcement activities based on the PMO requirements.

Changing the regulatory system to mandate compliance with the Preventive Controls provisions of part 117 would have a substantial economic impact on both state regulatory agencies and industry with no added public health protection. Industry will also experience operational challenges by attempting to comply with multiple regulations in addition to FSMA, such as: PMO or third-party certificate programs like GAP. VAAFM encourages FDA to consider the proven efficacy and efficiency of the long established cooperative milk safety program and provide an exemption for the Grade "A" milk industry from the preventive control provisions (subpart C) of Part 117.

Definitions

Definition of farm and harvesting: Activities traditionally conducted on farms (washing others RACs) now may be considered an operation that will subject a farm to inspection under PC and registration under the 2002 Bioterrorism (BT) Act.

The definition of "small business" is based on number of employees but options for the definition of "very small businesses" are based on income – these definitions should be consistent.

Certain commodities are considered "low risk", until the producers makes over a certain amount of money. What was the intention behind a monetary driver of risk as opposed to volume?

Please clarify on who will determine who is a "qualified individual" to prepare and carry out the preventative controls plan and if that "qualified individual" will need to be onsite at the processing facility.

Exemptions

Rule contains 12 different exemptions that are complicated; some examples below:

- Qualified Facility Exemption from preventive controls

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- The Tester Amendment provides an exemption for facilities with less than \$500,000 in sales yet must notify FDA and be subject to modified requirements that are also burdensome.
- On farm mixed type facility exemptions from preventive controls
 - FDA has established a list of low risk activities that will provide an exemption from preventive controls. Farm will still have to register for BT Act however. List is prescriptive and any deviation will result in farm being subject to full compliance with preventive controls.

Maple

VAAFM believes maple candies and maple cream should be exempt under the proposed rule as a “low risk food” similar to maple syrup. The production process for creating these products does not fit under the definition of “processing” as the only additional step is duration and temperature of heating maple syrup. The proposed rule is unclear if these value-added maple products are to be considered exempt from FSMA.

The Vermont Maple Sugar Makers Association has a voluntary certification program that VAAFM provides third-party services for. FDA could model their inspection after this program for those facilities that fall under the rule, depending on the ultimate definition for “very small businesses”.

Interaction with State Agencies

FSMA proposed rules do not clearly state or define oversight and responsibilities of state agencies. Currently, involvement and responsibility of state agencies in food safety varies by state and therefore multiple agencies could be involved and held responsible for implementing FSMA compliance and regulation. Depending on the number and types of facilities that fall under this rule and depending on what FDA delegates to states, Vermont State Agencies likely do not have adequate resources to carry out the inspections and possible environmental microbial testing required by this rule.